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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/331,204	08/20/1999	ROBERT TAM	216/013-US1	1379

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/331,204	TAM, ROBERT	
	Examiner	Art Unit	
	J. Douglas Schultz	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-17 and 19-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-10* is/are rejected.

7)☒ Claim(s) *11-17 and 19-25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed August 8, 2003 has been considered. Rejections and/or objections not reiterated from the previous office action mailed May 7, 2003 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Claim Objections

Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The invention of claim 13 is drawn to the aptamer of claim 1 comprising SEQ ID NO: 13, which is 12 nucleotides long. However, claim 1 has been amended to recite aptamers having a length of between 13 and 22 nucleic acids; thus, the 12mer claimed in claim 13 does not fall within the limits of claim 1, and thus fails to further limit claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7-17 and 19-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

The claims as originally filed were drawn to aptamer oligonucleotides 12 to 22 nucleotides in length. In addition, the specification contemplates such nucleotides 3 to 50, 8 to 30 or 12 to 22 in length, and discloses oligos of 12, 15, 18 and 22 nucleotides in length. In applicants' response dated August 8, 2003, applicants amended claim 1 to recite nucleic acids 13 to 22 nucleotides in length. However, following a review of specification, the examiner has been unable to locate where such support in the specification specifically exists for the limitation drawn to nucleotides with a lower limit of 13 rather than 12. Because there does not appear to be any reference in the specification for oligonucleotides comprising 13 to 22 nucleotides, but rather appears to support only those oligos comprising 12 to 22 nucleotides, the introduction of 13 as a lower limit appears to constitute new matter. Because the specification does not appear to support or disclose nucleotides that have the lower limit of 13, its entry essentially amounts to a negative limitation because such an amendment, if entered, would allow specifically for the exclusion of oligonucleotides that are 12 nucleotides long. Such exclusionary limitations must have basis in the original disclosure, as per M.P.E.P. § 2173.05(h):

> **Any negative limitation or exclusionary proviso must have basis in the original disclosure**. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff 'd mem., 738 F.2d 453 (Fed. Cir. 1984). **The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.** Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a prima facie case for lack of descriptive support. Ex parte Parks, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993). See MPEP § 2163 - § 2163.07(b) for a discussion of the written description requirement of 35 U.S.C. 112, first paragraph (emphasis supplied).

Since the specification appears to contemplate only 12 to 22 as a length limitation for the instant oligos, and does not contemplate 13 as a lower limit, the specification is not considered to provide support for the exclusion of oligonucleotides 12 nucleotides in length. Applicants have failed to provide any indication where support exists in the specification for such an amendment; should applicants feel that the specification supports such a limitation, applicants are invited to point out with particularity by page and line number where in the specification such support might exist for the lower limit of 13 nucleotides.

Claim Rejections - 35 USC 102/103

Applicant's arguments with respect to claims 1-4 and 6-10 have been considered but are largely moot in view of applicants' amendment and the new ground(s) of rejection set forth below. Those arguments considered to be relevant to the instant rejection are addressed at the bottom.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 and 103 that form the basis for the rejections under these sections made in this Office action:

> A person shall be entitled to a patent unless –
>
> 102(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
>
> 103(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, and 6-10 are rejected under 35 U.S.C. 102(e) and 103(a) as being anticipated and/or obvious by Rando et al. (U.S. Patent Number 5,567,604).

The claims of the above invention are drawn to nucleic acid aptamer compounds 13 to 22 nucleotides in length that reduce the expression of CD28 in an activated T-cell.

SEQ ID NO: 10 of Rando et al. (U.S. Patent Number 5,567,604) contains at least two G-quartets that are separated by four nucleotides. Although this reference does not specifically teach the function of reducing CD28 as claimed in the present application, the above-listed compound meets all the structural limitations as set forth in the instant claims. Thus, this sequence is considered to be substantially identical to applicant's claimed compounds, and, in the absence of evidence to the contrary, said compound is thus considered to possess the functional limitation of reducing the expression of CD28. Support for this conclusion is drawn from MPEP 2112:

> Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim **but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection**. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to

> product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims. *Emphasis supplied.*

In rejecting the claims of the above under 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a), a prima facie case has been established by the examiner whereby the burden of proof in showing that the claimed compounds are not anticipated by the compound(s) of the prior art as stated lies with the applicant, as per MPEP 2112.01:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Thus, in the absence of evidence to the contrary, the nucleic acid aptamer compound of claim 1-4 and 6-10 of the instant application are considered anticipated and/or obvious as outlined above.

The following is a response to applicant's arguments insofar as they pertain to the instant rejection of record.

Applicants have argued that the cited references are inconsistent with the sequence and function as presently claimed, because applicants assert that where nucleic acid sequences have an ambiguous sequence (e.g., certain percentage identity with a specific reference sequences or incorporating one or more undefined nucleobases), it is well established/recognized practice to describe the sequence in terms of its specific function (eg., hybridization or binding to a binding partner or effecting a particular biological function that is defined). Applicants conclude that therefore, the element

"...aptamer reduces CD28 expression in an activated human T-cell..." should be given proper patentable weight.

In response, it is noted that applicant is correct in stating that it is acceptable to claim sequences by function; in fact, it was not for this reason that the claims were rejected. Rather, the issue is that when a compound is claimed by both structural and functional elements as is the instant case, and that the structural elements are taught by the prior art which is otherwise silent as to the function, the compound is considered to possess the functional elements. Since the compound of Rando meets the structural limitations set forth in applicants claim, it is thus considered to possess the property of reducing CD28 expression, in the absence of evidence to the contrary. See M.P.E.P. citations above.

Allowable Subject Matter

Claims 11, 12, 14-17, and 19-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD

SEAN McGARRY
PRIMARY EXAMINER
1635